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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,998	SIMONS, MALCOLM J.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- *The MAILING DATE of this communication appears on the cov r sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-21,23 and 25-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-21,23 and 25-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Workgroup 1630, Art Unit 1634, and has been docketed to Primary Examiner Bradley L. Sisson.

Specification

2. The specification is objected to as documents have been improperly incorporated by reference. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

3. The following is a quotation of the appropriate paragraph of 37 CFR 1.67(b) that forms the basis of the objection under this section made in this Office action:

> A supplemental oath or declaration meeting the requirements of § 1.63 must be filed when a claim is presented for matter originally shown or described but not substantially embraced in the statement of invention or claims originally presented or when an oath or declaration submitted in accordance with § 1.53(f) after the filing of the specification and any required drawings specifically and improperly refers to an amendment which includes new matter. No new matter may be introduced into a nonprovisional application after its filing date even if a supplemental oath or declaration is filed. In proper situations, the oath or declaration here required may be made on information and belief by an applicant other than the inventor.

As a result of amendment(s) to the claim(s), the pending claim(s) no longer substantially embrace the invention as set forth in the statement of the invention and/or in the original claim(s). Accordingly, applicant is required to file a supplemental oath or declaration in response to this Office action.

4. The disclosure is objected to because of the following informalities: While applicant filed a Sequence Listing on 06 May 2003 which has been found to be acceptable and has been entered, the specification contains representations of nucleic acids that are not accompanied with the corresponding SEQ ID NO.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9, 11-21, 23, and 25-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

7. For convenience, claims 1, 13, 19, and 31, the only independent claims pending, are reproduced *infra*.

1. (currently amended) A method of determining at least one haplotype encompassing ~~of~~ a genetic coding locus comprising:

   (a) amplifying genomic DNA, wherein the amplified genomic DNA comprises a non-coding region sequence that is in genetic linkage with the genetic coding locus;

   (b) detecting one or more sequence variations in the non-coding region; and

   (c) using the one or more non-coding region sequence variations to determine ~~determining~~ at least one haplotype encompassing ~~of~~ the genetic coding locus.

13. (currently amended) A method for determining ~~determination of~~ at least one haplotype encompassing ~~of~~ a multi-allelic genetic coding locus comprising:

(a) amplifying genomic DNA with a primer pair that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said genetic coding locus and contains a sufficient number of non-coding region sequence nucleotides to produce an amplified DNA sequence characteristic of said at least one haplotype;

(b) analyzing the amplified DNA sequence to detect one or more sequence variations in the non-coding region; and

(c) using the one or more non-coding region sequence variations to determine ~~determining~~ at least one haplotype encompassing ~~of~~ the multiallelic genetic coding locus.

19. (currently amended) A method for determining ~~determination of~~ at least one haplotype encompassing ~~of~~ an HLA coding locus comprising:

(a) amplifying genomic DNA with a primer pair that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said HLA coding locus;

(b) analyzing the amplified DNA sequence to detect one or more sequence variations in the non-coding region; and

(c) using the one or more non-coding region sequence variations to determine ~~determining~~ at least one haplotype encompassing ~~of~~ the HLA coding locus.

31. (new) A method for genetic analysis, comprising:

a) amplifying a non-coding region of genomic DNA with a primer pair to produce an amplified DNA sequence, wherein said non-coding region is in genetic linkage with one or more coding region alleles that confer a trait;

b) analyzing the amplified DNA sequence to detect genetic variation in the non-coding region; and

c) correlating the genetic variation in the non-coding region with the trait conferred by the one or more coding region alleles.

8. For purposes of examination, the method of claims 1, 13, and 31, and the claims that depend therefrom, have been interpreted as encompassing a method whereby any haplotype in any life form is determined. Said method claims have also been interpreted as encompassing the effective determination of "genetic analysis" whereby any genetic disease, or susceptibility thereto, is identified and correlated with a "genetic variation" (claims 31-46). The term "individual" (claim 43) and "off spring" (claim 11) have been interpreted as encompassing any life form, human and non-human alike wherein said non-human encompass both plant and animal life forms that exist as single or multicellular entities.

9. As presently worded the claimed methods have also been interpreted as encompassing the use of any length and combination of primer as well as the generation of any size amplicon.

10. A review of the specification finds the following examples:

- Example 1, "Forensic Testing," pages 78-80;
- Example 2, "Paternity Testing," pages 80-82;
- Example 3, "Analysis of HLA DQA1 Locus," pages 83-88;
- Example 4, "Analysis of HLA DQA1 Locus," page 88;
- Example 5, "DQA1 Allele-Specific Amplification," page 89;
- Example 6, "Detection of Cystic Fibrosis," pages 89-90;
- Example 7, "Analysis of Bovine Leukocyte Antigen Class I," pages 90-91; and
- Example 8, "Preparation of Primers," pages 91-93.

11. A review of the specification fails to find an adequate description of the claimed methods wherein primers of any length are to be used or where amplicons of any length are to be generated. Page 15 of the disclosure teaches that the amplicons are to range in size from 800 to

2000 nucleotides. The specification does not teach the generation of larger or smaller sized nucleic acid fragments, nor the interpretation of nucleic acid fragments of different sizes. Attention is also directed to page 22 of the disclosure wherein is taught that the primers used in the claimed methods are to range in size from 8 to 30 nucleotides. Accordingly, the specification does not reasonably support the position that applicant contemplated, much less possessed, methods where primers of lengths outside of 8 to 30 nucleotides were to be used or where amplicons other than from 800 to 2,000 nucleotides in lengths are produced and evaluated. As presented above, the claimed method has been interpreted as encompassing the determination of any number of haplotypes in virtually any life form, and that the method can be used to identify whether such life form is susceptible to any disease. While the specification does provide a description of analyzing the HLS DQA1 locus in humans, the specification has not been found to provide the requisite description of such a broad genus as claimed. It would appear that applicant is attempting to assert that presently claimed genus is obvious in view of the disclosure. Obviousness, however, cannot be relied upon in satisfying the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

12. Acknowledgement is made of claims 26-46 having been added. A review of the amendment fails to locate any identification of where support for the new claim limitations is to be found in the original disclosure. Additionally, a review of the disclosure fails to locate said

support. Accordingly, and in the absence of convincing evidence to the contrary, claims 26-46 are deemed to introduce new matter into the disclosure.

13. Claims 1-9, 11-21, 23, and 25-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

As presented above, the specification has been found to set forth 8 examples. From these examples, the specification has been found to enable analysis of the human HLA DQA1 locus whereby the allele for cystic fibrosis can be detected. The specification has not been found to set forth a reproducible procedure whereby any haplotype of any life form can be determined, much less identify whether the life form is susceptible to any given disease. In order to practice such a method the skilled artisan would need appropriate starting materials, e.g., primers, as well as conditions under which they are to be used. Seemingly applicant is attempting to avoid disclosing the requisite starting materials by disclosing a general approach to producing primers. While such a disclosure may go toward fulfilling enablement requirements for a method of producing primers, the claimed method is not directed to a method of selecting primers. Rather, one must already have in their possession such e3ssential starting materials, and knowledge of the reaction conditions under which they are to be used. To seek broad protection, and not disclose such essential elements, i.e., starting materials and reaction conditions, unfairly shifts the burden of enablement from applicant to the public. The burden of enablement thereby placed upon the shoulders of the public is undue. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****

> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

The claimed method encompasses performing any number of amplification steps and where any level of stringency is used. To perform any number of amplification steps speak to the introduction of amplification artifacts due to error on the part of he polymerase as well as because of mis-priming, including primer-dimer formation. As a foundation, proper primer hybridization requires specific hybridization conditions. As set forth in Carrico, (US Patent 5,200,313) the extent and specificity of hybridization is affected by the following principal conditions:

1. The purity of the nucleic acid preparation.

2. Base compositions of the probe - G-C base pairs will exhibit greater thermal stability than A-T or A-U base pairs. Thus, hybridizations involving higher G-C content will be stable at higher temperatures.

3. Length of homologous base sequences- any short sequence of bases (e.g., less than 6 bases), has a high degree of probability of being present in many nucleic acids. Thus, little or no specificity can be attained in hybridizations involving such short sequences. From a practical standpoint, a homologous probe sequence will often be between 300 and 1000 nucleotides.

4. Ionic strength- the rate of reannealing increases as the ionic strength of the incubation solution increases. Thermal stability of hybrids also increases.

5. Incubation temperature- Optimal reannealing occurs at a temperature about 25 - 30 °C below the melting temperature for a given duplex. Incubation at temperatures significantly below the optimum allows less related base sequences to hybridize.

6. Nucleic acid concentration and incubation time- Normally, to drive the reaction towards hybridization, one of the hybridizable sample nucleic acid or probe nucleic acid will be present in excess, usually 100 fold excess or greater.

7. Denaturing reagents- the presence of hydrogen bond-disrupting agents, such as formaldehyde and urea, increases the stringency of hybridization.

8. Incubation- the longer the incubation time, the more complete will be the hybridization.

9. Volume exclusion agents- the presence of these agents, as exemplified by dextran and dextran sulfate, are thought to increase the effective concentrations of the hybridizing elements thereby increasing the rate of resulting hybridizations.

Further, subjecting the resultant hybridization product to repeated washes or rinses in heated solutions will remove non-hybridized probe. The use of solutions of decreasing ionic strength, and increasing temperature, e.g., 0.1X SSC for 30 minutes at 65 °C, will, with increasing effectiveness, remove non-fully complementary hybridization products.

14. Additionally, the invention clearly relates to the analysis of HLA alleles. The analysis of such alleles present additional difficulties. In support of this position, attention is directed to Canck et al. (US 2002/0197613 A1):

> The HLA system is the most polymorphic human genetic system yet known. HLA class I genes share a similar structure (from 5' to 3'): a S' untranslated flanking region, a first exon (exon 1) having a length of approximately 73 base pairs, a first intron (intron 1) having a length of approximately 130 base pairs, a second exon (exon 2), having a length of approximately 250 base pairs, a second intron (intron 2), having a length of approximately 272 base pairs, a third exon (exon 3), having a length of approximately 276 base pairs, a third intron (intron 3), having a length of approximately 588 base pairs and a fourth exon (exon 4), having a length of approximately 276 base pairs. Polymorphic substitutions within HLA class I alleles are mostly located in both exon 2 and exon 3, encoding the peptide binding groove of the class I molecule. . . Locus-specific primers are available for the amplification of these 1 kb amplicons. However, such large amplicons are difficult to amplify and show secondary structure formation resulting in inefficient hybridization of some probes. In addition, due to the emergence of new HLA-Class I alleles, certain allele combinations cannot be distinguished anymore by the detection of polymorphism's only in exon 2 and exon 3 and additional typing in exon 4 is required. This raises the need for the additional amplification of exon 4, resulting in an even larger amplicon. Therefore, a separate amplification of exon 2, exon 3 and/or exon 4 would be desired resulting in amplification products that enable a more efficient typing of HLA class I alleles. However, as locus-specific primer annealing sites are scarce and cannot be found in exon 2, exon 3 or exon 4, the separate and locus-specific amplification of exon 2, exon 3 and/or exon 4 of HLA-A, HLA-B or HLA-C is not that evident. (Emphasis added)

Attention is also directed to Baxter-Lowe et al.:

> The polymerase chain reaction (PCR) process, as described in Mullis U.S. Pat. No. 4,683,202, issued Jul. 28, 1987, allows the amplification of genomic DNA and has given rise to more convenient HLA typing procedures. HLA-DQ alpha and HLA-DP alpha and beta genes have been amplified, and then sequenced or hybridized with oligonucleotide

> probes. See Saiki et al., Nature, Vol. 324, pp. 163-166, 1986, Bugawan et al., J. Immunol., Vol. 141, No. 12, pp. 4024-4030, 1988, and Gyllensten et al., Proc. Natl. Acad. Sci. USA, Vol. 85, pp. 7652-7656, 1988. However, these methods have limited reliability due to the tendency of the probes to bind with greater or lesser specificity depending on the reaction conditions employed. (Emphasis added)

The specification is essentially silent as to how these art-recognized issues are to be overcome. Rather than setting forth an enabling disclosure, the public is being unfairly forced into enabling the claimed invention, assuming *arguendo*, that the claimed invention could be fully enabled. For the above reasons, and in the absence of convincing evidence to the contrary, applicant is urged to limit the claims to those embodiments for which patent protection has been awarded, i.e., claims of US Patent 5,192,659, with the added limitations that the method utilize primers of a defined size range and produce amplicons of a defined size range, *supra*.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-9, 11-21, 23, and 25-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No.

5,192,659. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass methods whereby HLA locus is detected.

17. Claims 1-9, 11-21, 23, and 25-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 5,612,179. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method of amplifying genomic DNA and analyzing the amplicons whereby the presence or absence of an allele is determined.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

20. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS